PARAmed
MEDICAL SYSTEMS

K121249

JUN 14 2012

Special 510(K) Summary

Date, 2012/05/17

The following Special 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(c).

Manufacturer Information

Manufacturer	Paramed Srl Corso Perrone 73R 16152 Genova, Italy
Establishment Reg. #	3004994584

807.92(a)(1)

Submitter Information

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807.92(a)(2)

Trade Name:	*Performance Package 01-4647-00 for MrJ System* *Performance Package 01-4647-01 for MrJ Inspire System*
Common Name:	Accessory for Magnetic resonance diagnostic system
Classification Name(s):	System, Nuclear Magnetic Resonance Imaging
Classification and class of device:	21 CFR 892.1000, class II
Classification Number:	*90MOS*

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807.92(a)(3)

Predicate Devices

Paramed	MrJ	K033507
Paramed	MrJ Extended	K080098
Paramed	MRJ Inspire	K100164

807.92(a)(4)

Description of the device that is the subject of the premarket notification submission

The *Performance Package* for MrJ series (MrJ and MRJ Inpsire) permanent magnet based MRI tomographs is a set of receiving coils intended to increase patient comfort while performing the same district examinations already performed by previously marketed receiving coils.

The two here proposed Kits differ only for what regards the connector to the magnet which for MrJ is flat and for MrJ Inspire it is round.

The components of the *Performance Package* (for MrJ and MRJ Inpsire) are the following:

- C-Spine dedicated coil (code 01-2023-00 if suitable for MrJ MRI and 01-2023-01 if suitable for MrJ Inspire MRI),

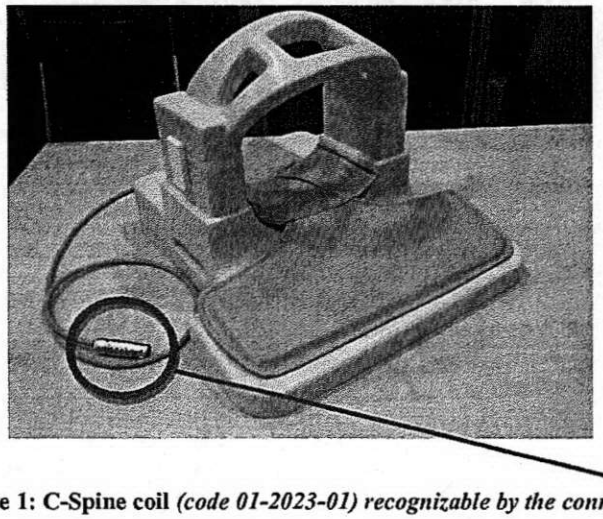

Figure 1: C-Spine coil *(code 01-2023-01) recognizable by the connector*

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- L-Spine dedicated coils (codes 01-2021-00 Small size; this model is suitable for MrJ MRI and 01-2022-01 Large size suitable for MrJ Inspire MRI),

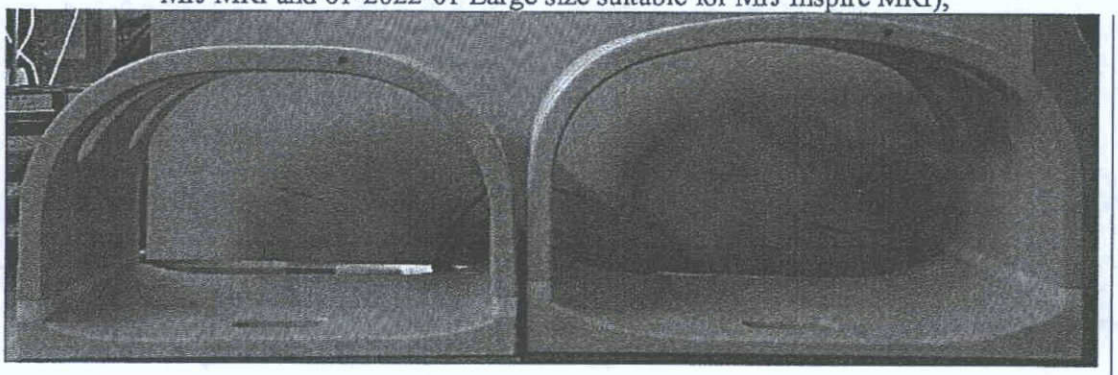
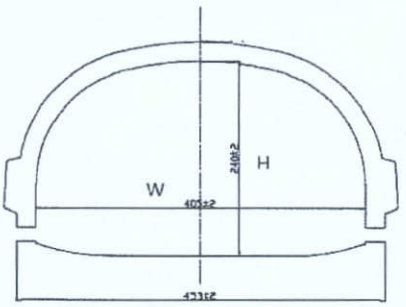


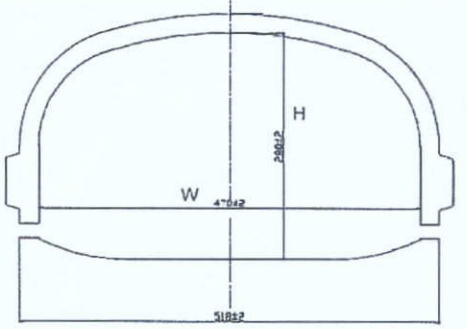
Figure 2: L-Spine small on the left and Large on the right

In particular the dimensions are different between the small and the large model according to the following table:

Model	L (mm)	W (mm)	H (mm)
L-Spine small 01-2021-00 01-2021-01	300 ±2	405 ±2	240 ±2
L-Spine Large 01-2022-00 01-2022-01	300 ±2	470 ±2	280 ±2



L-Spine small model dimensions



L-Spine Large model dimensions

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- MP_wrap multipurpose coil (code 01-2024-00 suitable for MrJ MRI and 01-2024-01 suitable for MrJ Inspire MRI); this coil can be employed as a back-up coil to fit most joints (such as, for instance but not limited to: knee, foot, ankle, elbow, wrist, hand...).

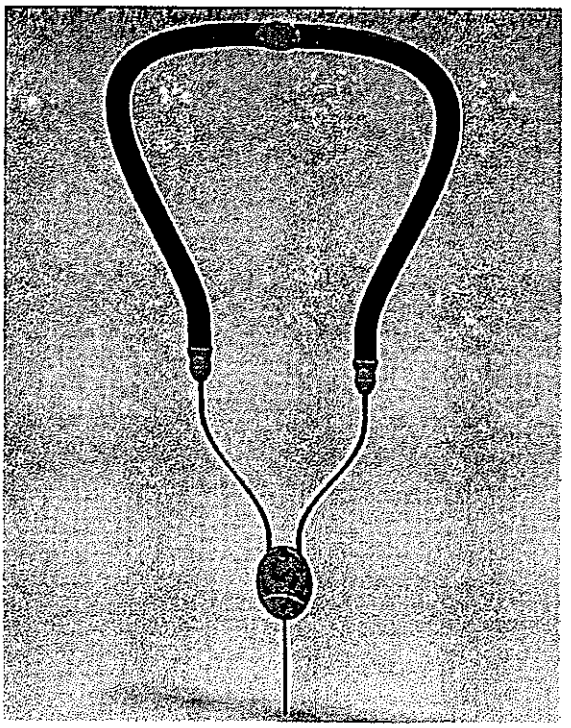

Figure 3: MP_Wrap coil

Explanation of how the device functions, the scientific concepts that form the basis for the device

The Proposed coils are receive coils.

The images produced by the device, when *Performance Package* is employed reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

The coils composing the system have been designed by outsourced qualified companies which then produce also part of the components. The suppliers have been selected and are controlled under Paramed's quality management system's procedures. The companies to which design and manufacturing of the receiving coils are being delegated are ISO 13485 certified. The design and manufacturing facilities supply the same or very similar components to other major MRI manufacturers which products are on the employed for the same purposes since many years.

Materials employed are:

- *The same as cleared previous coils (ref predicate K080098)*
- *PVC is added for C-Spine coil (01-2023-00, 01-2023-01), L-Spine small coil (01-2021-00, 01-2021-01), L-Large coil (01-2022-00, 01-2022-01),*

Device design

See Design section below

Significant physical and performance characteristics of the device

L-Spine Coils (small): *Models available 01-2021-00 and 01-2021-01. Receiving multichannel coils designed to host the Lumbar spine of small- medium size patients. This coil is rigid. The coil is composed by two parts to ease patient introduction. The conductive wires are laid down and are composed by copper windings wired to an electronic circuit which hosts the tuning and matching capacitors; an external cover in PVC prevents any dangerous contact of the patient with the electronic components. The design of this coil has been performed by outsourced qualified supplier which has certified UNI EN ISO 13485:2003 quality system.*

L-Spine Coils (large): *Models available 01-2022-00 and 01-2022-01. Receiving multichannel coils designed to host the Lumbar spine of medium- large size patients. This coil is rigid. The coil is composed by two parts to ease patient introduction. The conductive wires are laid down and are composed by copper windings wired to an electronic circuit which hosts the tuning and matching capacitors; an external cover in PVC prevents any dangerous contact of the patient with the electronic components. The design of this coil has been performed by outsourced qualified supplier which has certified UNI EN ISO 13485:2003 quality system.*

C-Spine Coils: *Models available 01-2023-00 and 01-2023-01. Receiving multichannel coils designed to host the Cervical spine of all sizes' patients. The coil is composed by two parts to ease patient introduction. The conductive wires are laid down and are composed by copper windings wired to an electronic circuit which hosts the tuning and matching capacitors; an external cover in PVC prevents any dangerous contact of the patient with the electronic components. The design of this coil has been performed by outsourced qualified supplier which has certified UNI EN ISO 13485:2003 quality system.*

MP_Wrap Coil: *Models available 01-2024-00 and 01-2024-01. Receiving single channel coil designed to be wrapped around the limbs to be examined. The conductive wires are laid down and are*

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MP_Wrap Coil: *Models available 01-2024-00 and 01-2024-01. Receiving single channel coil designed to be wrapped around the limbs to be examined. The conductive wires are laid down and are composed by copper windings wired to an electronic circuit which hosts the tuning and matching capacitors. an external cover in Polyamide prevents any dangerous contact of the patient with the electronic components. The design of this model has been performed by Paramed S.r.l. engineers and the manufacturing is performed by expert subcontractors.*

Physical properties

For what regards physical properties they are here resumed:

Item	S/N values Acceptable (NEMA procedures)	Signal/Noise as measured through NEMA Standard	S/N Accepted at final inspection (procedure limits)*
01-2021-00	≥ 16.5	18.68	31
01-2021-01			
01-2022-00	≥ 13.5	15.43	26
01-2022-01			
01-2023-00	≥ 17	18.14	40
01-2023-01			
01-2024-00	≥ 21	22.15	50
01-2024-01			

* the values accepted at final inspection are derived from those obtained according to NEMA procedure with scaling factors applied to take into account different sequence and different FOV.

807.92(a)(5)

Device Intended Use(s)

The intended use of the *Performance package* is to enable the permanent magnet based MRI systems designed by Paramed *(MrJ and MrJ Inspire)* to perform MR scan of the following districts: C-Spine one dedicated coil (code 01-2023), L-Spine two sizes of dedicated coils (codes 01-2021 and 01-2022), all other joints using a linear single channel coil named MP_wrap (code 01-2024) which is not aimed to specific districts but can fit most joints (such as, for instance, knee, foot, ankle, elbow, wrist, hand...). The *Performance package* inherits the same limitations of the System to which it is applied which is: only joint pathologies (no tumor, no angiography). *The Performance package enables the MRI System to which it is applied to acquire images of the districts being diagnosed in transverse, sagittal, coronal and oblique cross-sectional directions. The images which are produced correspond to spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.*

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Technological Characteristics

The *Performance package* is substantially equivalent to

- Paramed MrJ K033507 (C-spine coil and MP_wrap coil)
- Paramed MrJ Extended K080098 (L-Spine coils)
- When employed as an accessory for MrJ Inspire K100164 equivalence to all receiving coils is claimed

Neither the intended use nor the technological characteristics of this model differ from those of the referenced models.

807.92(b)(1)

The determination of substantial equivalence is based on the design similarities and final inspection report data here referenced and kept in Paramed's files.

A table of the equivalence between the two models is hereunder supplied for the most important specified characteristics:

Item	Description	Accessory to	Equivalent to	Description
01-2021-00	L-Spine Small *(°)*	MrJ *(*)*	01-2015-01	L-Spine Small
01-2021-01	L-Spine Small *(°)*	MrJ Inspire *(*)*	01-2015-02	L-Spine Small
01-2022-00	L-Spine Large *(°)*	MrJ *(*)*	01-2016-01	L-Spine Large
01-2022-01	L-Spine Large *(°)*	MrJ Inspire *(*)*	01-2016-02	L-Spine Large
01-2023-00	C-Spine *(°) (:)*	MrJ *(*)*	01-2002-01	C-Spine
01-2023-01	C-Spine *(°) (:)*	MrJ Inspire *(*)*	01-2002-02	C-Spine
01-2024-00	MP_Wrap (+)	MrJ *(*)*	01-2004-01	Shoulder single channel
01-2024-01	MP_Wrap (+)	MrJ Inspire *(*)*	01-2004-02	Shoulder single channel

(*) the only difference between the model which fits the MrJ and the MrJ Inspire is the connector of the coil to the magnet

(°) The design is different because the new coils are rigid. Moreover the new coils are at least dual channel coils (multiarray) while the previous ones were single channel this higher the homogeneity of the images in the FOV

(:) The C-Spine coil has been designed to increase patient comfort

(+) equivalence in design is claimed towards Shoulder coil but validation will be compared to knee coil because shoulder is not the mainly addressed district for this coil

The coils can be sold as a Kit, or as separate coils if the customer wants to buy only some of them.

807.92(b)(2)

For these coils the clinical output is documented at section Validation activities. No clinical study is necessary because the components are well known in the clinical practice and no innovation is here introduced unless a better ergonomic study of the shapes and the use of an external supplier for the design and functional part assembly.

807.92(b)(3)

On the basis of the internal Laboratory testing section below and of the test images performed both on phantoms and on healthy volunteers, we declare that the Multiaray Kit of receiving coils is at least as safe and effective as the predicate MrJ K033507 MrJ Extended K080098 and MrJ Inspire K100164 cleared devices with increased ergonomic performance, without losing effectiveness, as demonstrated both by the acceptable SNR and by the image quality (phantom and volunteer).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Luisella De Benedetti
Quality Manager
PARAmed S.r.L
Corso F. M. Perrone 73R
I-16152 GENOVA
ITALY

JUN 14 2012

Re: K121249
Trade/Device Name: Performance Package code 01-4647-00 for MrJ system and code 01-4647-01 for MrJ Inspire system
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: May 31, 2012
Received: May 31, 2012

Dear Ms. De Benedetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121249

Indications for Use

510(k) Number (if known): *K121249*

Device Name: *Performance Package* code 01-4647-00 *for MrJ system and code* 01-4647-01 *for MrJ Inspire system*

Indications for Use:

The intended use of the *Performance Package* is to enable the permanent magnet based MRI systems designed by Paramed *(MrJ and MrJ Inspire)* to perform MR scan of the following districts: C-Spine one dedicated coil (code 01-2023), L-Spine two sizes of dedicated coils (codes 01-2021 and 01-2022), all other joints using a linear single channel coil named MP_wrap (code 01-2024) which is not aimed to specific districts but can fit most joints (such as, for instance, knee, foot, ankle, elbow, wrist, hand...). The *Performance Package* inherits the same limitations of the System to which it is applied which is: only joint pathologies (no tumor, no angiography). The *Performance Package* enables the MRI System to which it is applied to acquire images of the districts being diagnosed in transverse, sagittal, coronal and oblique cross-sectional directions. The images which are produced correspond to spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121249